

# Inducing and maintaining normothermia using temperature modulation devices to improve outcomes after stroke or subarachnoid haemorrhage

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg701](https://www.nice.org.uk/guidance/ipg701)

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

# 1 Recommendations

- 1.1 Evidence on the safety and efficacy of inducing and maintaining normothermia using temperature modulation devices to improve outcomes after stroke or subarachnoid haemorrhage is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out what [only in research means](#) on the [NICE interventional procedures guidance page](#).
- 1.2 Further research should preferably be randomised controlled trials. It should report details of patient selection (including cause of fever, severity of stroke and neurological injury), method and duration of cooling, time from the neurological injury and onset of fever to starting cooling, complications related to the procedure and the device, neurological outcomes assessed using validated measures, and patient-reported outcomes (including quality of life) in the long term.

## 2 The condition, current treatments and procedure

### The condition

- 2.1 Stroke (ischaemic stroke and intracerebral haemorrhage) is an acute neurological event presumed to be vascular in origin and causing cerebral ischaemia, cerebral infarction or cerebral haemorrhage. Subarachnoid haemorrhage (SAH) is a haemorrhage from a cerebral blood vessel, aneurysm or vascular malformation into the subarachnoid space.
- 2.2 Both conditions can interrupt blood flow to the brain, damage brain cells and cause abnormalities of thermoregulation and an abnormally high body temperature (neurogenic fever). The abnormally high temperature may result in secondary neurological injury and is associated with worse outcomes, greater morbidity and mortality.

### Current treatments

- 2.3 Diagnosis and initial management of stroke is described in [NICE's guideline on stroke and transient ischaemic attack in over 16s](#). Current treatments for managing fever after stroke or SAH include identifying and treating a cause, antipyretic medications and standard physical methods of cooling such as fans and cooling blankets to lower body temperature.

### The procedure

- 2.4 In this procedure, a temperature modulation device is used to maintain the patient's core temperature within normal limits ( $37.0\pm 0.5^{\circ}\text{C}$ ). Either surface techniques (such as heat exchange cooling pads) or internal techniques (such as an endovascular cooling device) may be used. Heat is exchanged between the patient and the device to allow the body temperature to be controlled to a pre-

set point determined by the clinician.

- 2.5 This procedure aims to reduce brain injury and improve neurological outcomes after stroke or SAH by maintaining normothermia with precise temperature control.

## 3 Committee considerations

### The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 7 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 3 non-randomised comparative studies and 3 case series. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, reduction in disability and neurological injury.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: mortality, cardiovascular complications, worsening neurological outcomes, shivering and infection.
- 3.4 Patient commentary was sought but none was received.

### Committee comments

- 3.5 The committee noted that the evidence reviewed compared the use of special temperature modulation devices to achieve normothermia with conventional fever management, including antipyretic medications and standard cooling (such as

surface cooling blankets).

- 3.6 The committee noted that the evidence reviewed showed many complications, but it was difficult to identify whether these were related to the neurological injury or the procedure.
- 3.7 The committee noted that there are various techniques used and that the safety profiles of the various techniques may be different.

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## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).